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11 Attorneys for Defendants  
12 COSTCO WHOLESALE CORP. and  
13 NBTY, INC.

14 UNITED STATES DISTRICT COURT  
15 SOUTHERN DISTRICT OF CALIFORNIA  
16

17 TATIANA KOROLSHTEYN, on behalf  
18 of herself and all others similarly  
19 situated,

20 Plaintiff,

21 v.

22 COSTCO WHOLESALE  
23 CORPORATION and NBTY, INC.,  
24

25 Defendants.  
26  
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28

CASE NO.: 3:15-CV-00709-CAB-RBB

**DECLARATION OF DR. SUSAN  
MITMESSER IN SUPPORT OF  
DEFENDANTS' MOTION FOR  
SUMMARY JUDGMENT**

Date: June 6, 2017

Time: 10:00 a.m.

Judge: Hon. Cathy Ann Bencivengo

Courtroom: 4C

**[REDACTED VERSION]**

**DECLARATION OF SUSAN H. MITMESSER**

I, Susan H. Mitmesser, declare:

1. I am currently employed by The Nature's Bounty Co. f/k/a NBTY, Inc. ("NBTY"). My current title is Senior Director of Nutrition and Scientific Affairs. I have been retained by Defendants in this matter to provide opinions and testimony concerning the efficacy of Ginkgo Biloba. I make this declaration of my own personal knowledge. If I were called to testify, I could and would testify competently to the matters herein.

2. Attached here to as Exhibit A is a true and correct copy of my expert report provided in this case, which sets forth my opinions. I have provided my opinions to a reasonable degree of medical and scientific certainty.

3. NBTY maintains confidential "Structure Function Files," which include information regarding the substantiation of every claim made on our product labels and the functionality of the product's ingredients, including one for the active ingredients in the Ginkgo Products. While the information in these files may be publicly available, the company treats its unique collection of publicly available studies and information as proprietary and confidential.

4. For the active ingredient in the Ginkgo Products—Ginkgo Biloba extract standardized to contain 24% glycosides and 6% terpenes—the Structure Function File assembles scientific articles and reports relevant to the properties and benefits of Ginkgo Biloba.

5. Among the studies relied upon by NBTY in support of the claims made on the labels of the Ginkgo products are the following eighteen studies, which are part of the Ginkgo Biloba Structure Function File and referenced in my expert report. True and correct copies of these eighteen studies are attached hereto as Exhibits B through S:

1 Exhibit B: G. Vorberg, *Ginkgo Biloba Extract (GBE\*): A Long-Term*  
 2 *Study of Chronic Cerebral Insufficiency in Geriatric Patients* (1985).

- 3 i. In this study, 112 patients with chronic cerebral insufficiency (i.e.,  
 4 decreased blood supply to the brain) were given 120 mg/day in an  
 5 open-label one-year trial. The authors reported statistically  
 6 significant regression of the major symptoms of vertigo, headache,  
 7 tinnitus, short-term memory, vigilance, and mood disturbances.
- 8 ii. In my professional opinion, this study provides evidence for  
 9 increased blood flow to the brain which helped ameliorate the  
 10 various symptoms that had resulted from insufficient blood flow to  
 11 the brain.

12 Exhibit C: J. Mehlsen, *Effects of a Ginkgo biloba extract on forearm*  
 13 *haemodynamics in healthy volunteers* (2002).

- 14 i. This was a randomized, double-blinded cross-over design in 16  
 15 healthy subjects. The subjects were given either Ginkgo biloba or  
 16 a placebo. The authors concluded that oral treatment of Ginkgo  
 17 biloba was able to dilate forearm blood vessels causing increments  
 18 in regional blood flow without changing blood pressure levels in  
 19 healthy subjects.
- 20 ii. In my professional opinion, this study provides evidence for  
 21 increased blood flow to the extremities and throughout the body.

22 Exhibit D: P. Fies, et al., *Ginkgo extra in impaired vision—treatment of*  
 23 *visual impairment due to senile dry macular degeneration with the special*  
 24 *extract EGb 761®* (2002).

- 25 i. This was a double-blind, controlled study involving 99 patients  
 26 with impaired vision due to senile dry macular degeneration.  
 27 Patients were given either 240 mg/day or 60 mg/day of Ginkgo  
 28 Biloba extract. The authors reported seeing “marked

1 improvement” in vision in both groups after four weeks with  
 2 greater improvement in the 240 mg/day group.

- 3 ii. In my professional opinion, this study provides evidence for  
 4 increased blood flow to the eyes which would also be indicative of  
 5 increased blood flow to the brain.

6 Exhibit E: U. Bauer, *6-Month Double-blind Randomised Clinical Trial of*  
 7 *Ginkgo biloba Extract versus Placebo in Two Parallel Groups in Patients*  
 8 *Suffering from Peripheral Arterial Insufficiency* (1984)

- 9 i. This was a double-blind, placebo-controlled study involving 79  
 10 patients over a 6 month period. The authors reported a “clear  
 11 beneficial therapeutical effect” related to Ginkgo in patients  
 12 suffering from peripheral arteriopathy stage II. The authors also  
 13 reported improvement in peripheral arterial blood flow.

- 14 ii. In my professional opinion, this study provides evidence for  
 15 improvement in peripheral arterial blood flow.

16 Exhibit F:

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 21 [REDACTED]  
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 24 [REDACTED]  
 25 [REDACTED]  
 26 [REDACTED]  
 27 [REDACTED]  
 28 [REDACTED]

1 Exhibit G: P. Le Bars, et al., *A Placebo-Controlled, Double-Blind*  
 2 *Randomized Trial of an Extract of Ginkgo Biloba for Dementia* (1997).

- 3 i. This was a 52-week intent-to-treat study involving mildly to  
 4 severely demented outpatients with Alzheimer's disease or multi-  
 5 infarct dementia. The patients were given either 120 mg/day of  
 6 Ginkgo Biloba or a placebo. The authors reports that Ginkgo  
 7 Biloba was capable of stabilizing, and in a number of cases,  
 8 improving the cognitive performance and the social functioning of  
 9 demented patients for 6 months to 1 year.
- 10 ii. In my professional opinion, this study provides evidence for the  
 11 fact that Ginkgo can help support healthy brain function.

12 Exhibit H: [REDACTED]  
 13 [REDACTED]  
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 28 [REDACTED]

1 Exhibit I: [REDACTED]

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13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 Exhibit J: S. Zhang, et al., *Effect of Western medicine therapy assisted by*  
 17 *Ginkgo biloba tablet on vascular cognitive impairment of none dementia*  
 18 (2012).

- 19 i. This study involved 80 patients with vascular cognitive impairment  
 20 of none dementia (VCIND) (i.e., patients that were cognitively  
 21 impaired but had not yet reached the dementia stage). The 80  
 22 patients were divided into two groups; one group received 75 mg  
 23 aspirin three times a day for 3 months and the other group was  
 24 given 75 mg combined with 120 mg of Ginkgo biloba three times a  
 25 day for 3 months. The authors reported that scores of executive  
 26 ability, attention, abstract, delayed memory, and orientation in the  
 27 MoCA were significantly increased as compared with baseline and  
 28 the aspirin-only group. In addition, blood flow velocity of anterior

1 cerebral artery increased significantly as compared with baseline  
2 and the aspirin-only group.

- 3 ii. In my professional opinion, this study provides evidence that  
4 Ginkgo biloba can not only have positive effects on memory and  
5 cognitive function but can also increase blood flow velocity to the  
6 brain.

7 Exhibit K:

8 [REDACTED]  
9 [REDACTED]

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18 Exhibit L:

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1 Exhibit M: D. O. Kennedy, et al., *The dose-dependent cognitive effects of*  
 2 *acute administration of Ginkgo biloba to healthy young volunteers* (2000).

3 i. This was a double-blind, placebo-controlled, crossover study  
 4 intended to test the efficacy of an acute administration of Ginkgo  
 5 biloba (i.e., a single dose). Twenty young and healthy participants  
 6 received 120 mg, 240 mg, and 360 mg of Ginkgo and were  
 7 assessed using a computerized test battery at dosing and then at 1,  
 8 2.5, 4, and 6 hours thereafter on four aspects of cognitive  
 9 performance. Based on the results of the study which showed  
 10 improvement on the “speed of attention” factor for the 240 mg and  
 11 360 mg dosage, the authors concluded that their “results show that  
 12 acute Ginkgo biloba administration enhances cognitive  
 13 performance in healthy young adults.”

14 ii. In my professional opinion, this study provides evidence for the  
 15 fact that Ginkgo can help support healthy brain function.

16 Exhibit N: [REDACTED]  
 17 [REDACTED]  
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26 Exhibit O: [REDACTED]  
 27 [REDACTED]  
 28 [REDACTED]



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Exhibit P: [REDACTED]

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Exhibit Q: [REDACTED]

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Exhibit R: [REDACTED]

[REDACTED]

Exhibit S: [REDACTED]

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[REDACTED]

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Executed this 4<sup>th</sup> day of May 2017, at Hillsdale, Michigan.



— Susan H. Mitmesser —